

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28240

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 48/00

US CL : 514/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/44

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	REVENKOVA et al. Novel meiosis-specific isoform of mammalian SMC1. Molecular and Cellular Biology October 2001, Vol., 21(20): pp. 6984-6998 (see entire document).	1, 2, 10-13, 16, 30, 31, 34-36, 43-44, 48-49
A	WO 01/26664 A2 (MITCHELL et al.) 19 April 2001 (19.04.2001) (see entire document).	1, 2, 10-13, 16, 30, 31, 34-36, 43-44, 48-49

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

04 May 2005 (04.05.2005)

Date of mailing of the international search report

17 MAY 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Jon B. Ashen

Telephone No. 703-308-1235

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28246

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 134
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Please See Continuation Sheet
3. ☒ Claims Nos.: 17-19 and 29
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1, 2, 10-13, 16-19, 29-31, 34-36, 43-44, 48-49, 134 and SEQ ID NO: 1.

Remark on Protest

☐

The additional search fees were accompanied by the applicant's protest.

☐

No protest accompanied the payment of additional search fees

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/28240

Continuation of Box II Reason 2:

Claim 134 is drawn to a method according to claim 1 or 10 substantially as described and illustrated herein. No meaningful search of this claim can be performed because the subject matter that is encompassed by a method that is substantially like another method cannot be determined.

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

The following groups are set forth in reconsideration of the Lack of Unity held in this Application and transmitted on the Form 206 mailed 10 March 2005.

Group 1, claim(s) 1, 2, 10-13, 16-19, 29-31, 34-36, 43-44, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 1.

Group 2, claim(s) 1, 2, 10-13, 16-19, 29-31, 34-36, 43-44, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 3.

Group 3, claim(s) 1, 2, 10, 14-19, 29, 32-35, 37, 43-44, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 1.

Group 4, claim(s) 1, 2, 10, 14-19, 29, 32-35, 37, 43-44, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 3.

Group 5, claim(s) 1, 2, 10-13, 16-19, 29-31, 34-36, 43, 45, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with a small molecule antagonist of SMC1B.

Group 6, claim(s) 1, 2, 10-13, 16-19, 29-31, 34-36, 43, 46, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with a peptidomimetic antagonist of SMC1B.

Group 7, claim(s) 1, 2, 10-13, 16-19, 29-31, 34-36, 43, 47, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an anti-SMC1B antibody.

Group 8, claim(s) 1, 2, 10, 14-19, 29, 32-35, 37, 43, 45, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with a small molecule antagonist of SMC1B.

Group 9, claim(s) 1, 2, 10, 14-19, 29, 32-35, 37, 43, 46, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with a peptidomimetic antagonist of SMC1B.

Group 10, claim(s) 1, 2, 10, 14-19, 29, 32-35, 37, 43, 47, 48-49 and 134, drawn to a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an anti-SMC1B antibody.

Group 11, claim(s) 3-9, 70-72, 92, 93, 98, 99, 100, 119, 121-124, 126-128, 135, 136, drawn to an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 1, an expression construct comprising a nucleic

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/28240

acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

Group 12, claim(s) 3-9, 70-72, 92, 93, 98, 99, 100, 119, 121-124, 126-128, 135, 136, drawn to an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 3, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

Group 13, claim(s) 3-9, 70-72, 92, 93, 98, 99, 100, 119, 121-122, 125-128, 135, 136, drawn to an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 1, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

Group 14, claim(s) 3-9, 70-72, 92, 93, 98, 99, 100, 119, 121-122, 125-128, 135, 136, drawn to an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 3, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

Group 15, claim(s) 20-22, 26-27, 34, 50-51, 53-59, 63-65, 67, drawn to a method of treating infertility in a male animal comprising administering exogenous SMC1B or a SMC1B polypeptide.

Group 16, claim(s) 20-22, 26-27, 34, 50-51, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a nucleic acid construct that encodes the SMC1B polypeptide.

Group 17, claim(s) 20-22, 26-27, 34, 50-51, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a small molecule agonist of SMC1B.

Group 18, claim(s) 20-22, 26-27, 34, 50-51, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a peptidomimetic agonist of SMC1B.

Group 19, claim(s) 20, 23-27, 32-34, 50, 52, 53-59, 63-65, 67, drawn to a method of treating infertility in a female animal comprising administering exogenous SMC1B or a SMC1B polypeptide.

Group 20, claim(s) 20, 23-27, 32-34, 50, 52, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a nucleic acid construct that encodes the SMC1B polypeptide.

Group 20, claim(s) 20, 23-27, 32-34, 50, 52, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a small molecule agonist of SMC1B.

Group 22, claim(s) 20, 23-27, 32-34, 50, 52, 53-59, 63-65, 67, 94-95, 101-102, drawn to a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a peptidomimetic agonist of SMC1B.

Group 23, claim(s) 66-67, drawn to a method of diagnosis resulting from abnormal levels of SMC1B comprising detecting the presence or amount of expression or activity of an SMC1B polypeptide in a sample.

Group 24, claim(s) 66-67, 76-78, drawn to a method of diagnosis resulting from abnormal levels of SMC1B comprising detecting the presence or amount of expression or activity of a nucleic acid encoding a SMC1B polypeptide in a sample.

Group 25, claim(s) 28, 29, 68, 69, 72, 135, 136, drawn to a composition that induces SMC1B expression or activity comprising exogenous SMC1B or an SMC1B polypeptide and a pharmaceutically acceptable carrier.

Group 26, claim(s) 28, 29, 68, 69, 72, 92, 93, 98, 100, 119-120, 122-124, 126-128, 135, 136, drawn to a composition that induces SMC1B expression or activity comprising a nucleic acid construct that encodes SMC1B, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in a sense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

Group 27, claim(s) 28, 29, 68, 69, 72, 92, 93, 98, 100, 119-120, 122, 125-128, 135, 136, drawn to a composition that induces SMC1B expression or activity comprising a nucleic acid construct that encodes SMC1B, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in a sense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28240

Group 28, claim(s) 28, 29, 68, 69, 72, 135, 136, drawn to a composition that induces SMC1B expression or activity comprising a small molecule agonist of SMC1B.

Group 29, claim(s) 28, 29, 68, 69, 72, 135, 136, drawn to a composition that induces SMC1B expression or activity comprising a peptidomimetic agonist of SMC1B.

Group 30, claim(s) 74, 75, drawn to a diagnostic reagent comprising a detectably labeled polynucleotide encoding the SMC1B polypeptide or a fragment, variant or homolog thereof.

Group 31, claim(s) 79-80, 82, 84-86, 88, 96, drawn to a method for screening or identifying agents that increase meiosis or increase SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that increases the expression of activity of SMC1B.

Group 32, claim(s) 79, 81-82, 84-87, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that reduces the expression of activity of SMC1B.

Group 33, claim(s) 79-80, 83-86, 88, 96, drawn to a method for screening or identifying agents that increase meiosis or increase SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that increases the expression of activity of SMC1B.

Group 34, claim(s) 79, 81, 83-87, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that reduces the expression of activity of SMC1B.

Group 35, claim(s) 79, 81-82, 84-86, 89, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is an antibody of SMC1B.

Group 36, claim(s) 79, 81, 83-86, 89, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is an antibody of SMC1B.

Group 37, claim(s) 79, 81-82, 84-86, 90, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a small molecule antagonist of SMC1B.

Group 38, claim(s) 79, 81, 83-86, 90, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a small molecule antagonist of SMC1B.

Group 39, claim(s) 79, 81-82, 84-86, 91, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is peptidomimetic antagonist of SMC1B..

Group 40, claim(s) 79, 81, 83-86, 91, 96-97, drawn to a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a peptidomimetic antagonist of SMC1B.

Group 41, claim(s) 92, 93-95, 98-102, 131-133, drawn to a composition comprising a candidate modulating agent that inhibits that is an antibody of SMC1B.

Group 42, claim(s) 92, 93-95, 98-102, drawn to a composition comprising a candidate modulating agent that inhibits meiosis that is a small molecule antagonist of SMC1B.

Group 43, claim(s) 92, 93-95, 98-102, drawn to a composition comprising a candidate modulating agent that inhibits meiosis that is a peptidomimetic antagonist of SMC1B.

Group 44, claim(s) 103-105, drawn to a transgenic non-human animal.

Group 45, claim(s) 106-109, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining the effect of the treatment by sperm count.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28240

Group 46, claim(s) 106-108, 110, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining testicular size.

Group 47, claim(s) 106-108, 111, 112, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining oocyte morphology.

Group 48, claim(s) 106-108, 111, 113, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining sperm cell morphology.

Group 49, claim(s) 106, 114, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the effect on chromosome morphology.

Group 50, claim(s) 106, 115, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the ability of chromosomes to pair.

Group 51, claim(s) 106, 116, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the ability of the mice to mate and produce offspring.

Group 52, claim(s) 106, 117, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining the ability of the mice to have normal estrus cycles.

Group 53, claim(s) 106, 118, drawn to a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining ovarian morphology.

Group 54, claim(s) 129 and 130, drawn to a device comprising a membrane suitable for implantation.

Group 55, claim(s) 137, drawn to a compound for inducing the expression of a heterologous gene in a germ cell comprising a SMC1B promoter comprising SEQ ID NO: 12 operably linked to said heterologous gene.

Group 56, claim(s) 137, drawn to a compound for inducing the expression of a heterologous gene in a germ cell comprising a SMC1B promoter comprising SEQ ID NO: 13 operably linked to said heterologous gene.

Group 57, claim(s) 138, drawn to a method of inducing expression of a heterologous gene in a germ cell comprising contacting with the expression construct comprising SEQ ID NO: 12.

Group 58, claim(s) 138, drawn to a method of inducing expression of a heterologous gene in a germ cell comprising contacting with the expression construct comprising SEQ ID NO: 13.

The inventions listed as Groups 1-64 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below:

The inventions listed as Groups 1-64 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed polynucleotide sequences, the Markush group shall be regarded as being of similar nature when:

- (A) all alternatives have a common property or activity and
- (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant antisense sequences as claimed in Claim 2 are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. The first claimed invention in this application is drawn to a method of inhibiting the expression of SMC1B by contacting with an SMC1B antisense nucleic acid or an antisense compound 8-80 nucleotides in length targeted to SEQ ID NO: 1 or SEQ ID NO: 3. The antisense sequences of the instant application target and modulate expression of the SCMB1 gene in either mouse (SEQ ID NO: 1) or human (SEQ ID NO: 3).

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28240

However, each antisense sequence behaves in a different way in the context of the claimed invention. Each antisense compound that targets SEQ ID NO: 1 or SEQ ID NO: 3, targets a different and specific region of that sequence and inhibits the expression of the gene to varying degrees. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved. Therefore, although the instant polynucleotide sequences are characterized as SCMB1 antisense nucleic acids, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the antisense polynucleotide sequences of the instant application is lacking and each antisense polynucleotide sequence claimed is considered to constitute a special technical feature.

As the antisense polynucleotide sequences of the instant invention are recited in the first claimed invention, Applicants will obtain a search of the first sequence listed in the claim. For every other sequence applicants wish to have searched, applicants need to elect the sequence and pay an additional fee.

If the sequences are recited in the second or subsequent claimed invention, Applicants will need to elect the group and pay the fee to obtain a search of the first sequence listed in the claims encompassed by the second or subsequent group. For every other sequence in the second/subsequent group that applicants wish to have searched, applicants need to elect the sequence and pay an additional fee.

The special technical feature of group 1 is a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 1.

The special technical feature of group 2 is a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 3.

The special technical feature of group 3 is a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 1.

The special technical feature of group 4 is method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an antisense nucleic acid that hybridizes to SEQ ID NO: 3.

The special technical feature of group 5 is a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with a small molecule antagonist of SMC1B.

The special technical feature of group 6 is a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with a peptidomimetic antagonist of SMC1B.

The special technical feature of group 7 is a method for inducing infertility or inhibiting meiosis in a male animal comprising inhibiting SMC1B expression or activity with an anti-SMC1B antibody.

The special technical feature of group 8 is a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with a small molecule antagonist of SMC1B.

The special technical feature of group 9 is a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with a peptidomimetic antagonist of SMC1B.

The special technical feature of group 10 is a method for inducing infertility or inhibiting meiosis in a female animal comprising inhibiting SMC1B expression or activity with an anti-SMC1B antibody.

The special technical feature of group 11 is an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 1, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 12 is an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 3, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 13 is an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 1, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in an antisense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 14 is an antisense nucleic acid of SMC1B or an antisense compound targeted to a nucleic acid molecule encoding SMC1B of SEQ ID NO: 3, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/28240

or variant thereof in an antisense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 15 is a method of treating infertility in a male animal comprising administering exogenous SMC1B or a SMC1B polypeptide.

The special technical feature of group 16 is a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a nucleic acid construct that encodes the SMC1B polypeptide.

The special technical feature of group 17 is a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a small molecule agonist of SMC1B.

The special technical feature of group 18 is a method of treating infertility in a male animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a peptidomimetic agonist of SMC1B.

The special technical feature of group 19 is a method of treating infertility in a female animal comprising administering exogenous SMC1B or a SMC1B polypeptide.

The special technical feature of group 20 is to a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a nucleic acid construct that encodes the SMC1B polypeptide.

The special technical feature of group 21 is a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a small molecule agonist of SMC1B.

The special technical feature of group 22 is a method of treating infertility in a female animal comprising administering an agent that induces SMC1B expression or activity wherein that agent is a peptidomimetic agonist of SMC1B.

The special technical feature of group 23 is a method of diagnosis resulting from abnormal levels of SMC1B comprising detecting the presence or amount of expression or activity of an SMC1B polypeptide in a sample.

The special technical feature of group 24 is a method of diagnosis resulting from abnormal levels of SMC1B comprising detecting the presence or amount of expression or activity of a nucleic acid encoding a SMC1B polypeptide in a sample.

The special technical feature of group 25 is a composition that induces SMC1B expression or activity comprising exogenous SMC1B or an SMC1B polypeptide and a pharmaceutically acceptable carrier.

The special technical feature of group 26 is a composition that induces SMC1B expression or activity comprising a nucleic acid construct that encodes SMC1B, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in a sense orientation, further comprising a heterologous, testis specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 27 is a composition that induces SMC1B expression or activity comprising a nucleic acid construct that encodes SMC1B, an expression construct comprising a nucleic acid encoding a SMC1B polypeptide, fragment or variant thereof in a sense orientation, further comprising a heterologous, oocyte specific promoter, a composition comprising said construct and a recombinant host cell comprising said construct.

The special technical feature of group 28 is a composition that induces SMC1B expression or activity comprising a small molecule agonist of SMC1B.

The special technical feature of group 29 is a composition that induces SMC1B expression or activity comprising a peptidomimetic agonist of SMC1B.

The special technical feature of group 30 is a diagnostic reagent comprising a detectably labeled polynucleotide encoding the SMC1B polypeptide or a fragment, variant or homolog thereof.

The special technical feature of group 31 is a method for screening or identifying agents that increase meiosis or increase SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that increases the expression or activity of SMC1B.

The special technical feature of group 32 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that reduces the expression or activity of SMC1B.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/28240

The special technical feature of group 33 is a method for screening or identifying agents that increase meiosis or increase SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that increases the expression of activity of SMC1B.

The special technical feature of group 34 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a nucleic acid construct that reduces the expression of activity of SMC1B.

The special technical feature of group 35 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is an antibody of SMC1B.

The special technical feature of group 36 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is an antibody of SMC1B.

The special technical feature of group 37 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a small molecule antagonist of SMC1B.

The special technical feature of group 38 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a small molecule antagonist of SMC1B.

The special technical feature of group 39 is a method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a male germ cell comprising contacting with a candidate modulating agent that is a peptidomimetic antagonist of SMC1B..

The special technical feature of group 40 is method for screening or identifying agents that decrease meiosis or decrease SMC1B expression or activity in a female germ cell comprising contacting with a candidate modulating agent that is a peptidomimetic antagonist of SMC1B.

The special technical feature of group 41 is a composition comprising a candidate modulating agent that inhibits meiosis that is an antibody of SMC1B.

The special technical feature of group 42 is a composition comprising a candidate modulating agent that inhibits meiosis that is a small molecule antagonist of SMC1B.

The special technical feature of group 43 is a composition comprising a candidate modulating agent that inhibits meiosis that is a peptidomimetic antagonist of SMC1B.

The special technical feature of group 44 is a transgenic non-human animal.

The special technical feature of group 45 is a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining the effect of the treatment by sperm count.

The special technical feature of group 46 is a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining testicular size.

The special technical feature of group 47 is a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining oocyte morphology.

The special technical feature of group 48 is a method of evaluating a fertility treatment comprising administering the treatment to a male transgenic mouse and determining sperm cell morphology.

The special technical feature of group 49 is a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the effect on chromosome morphology.

The special technical feature of group 50 is a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the ability of chromosomes to pair.

The special technical feature of group 51 is a method of evaluating a fertility treatment comprising administering the treatment to a transgenic mouse and determining the ability of the mice to mate and produce offspring.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/28240

The special technical feature of group 52 is a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining the ability of the mice to have normal estrus cycles.

The special technical feature of group 53 is a method of evaluating a fertility treatment comprising administering the treatment to a female transgenic mouse and determining ovarian morphology.

The special technical feature of group 54 is a device comprising a membrane suitable for implantation.

The special technical feature of group 55 is a compound for inducing the expression of a heterologous gene in a germ cell comprising a SMC1B promoter comprising SEQ ID NO: 12 operably linked to said heterologous gene.

The special technical feature of group 56 is a compound for inducing the expression of a heterologous gene in a germ cell comprising a SMC1B promoter comprising SEQ ID NO: 13 operably linked to said heterologous gene.

The special technical feature of group 57 is a method of inducing expression of a heterologous gene in a germ cell comprising contacting with the expression construct comprising SEQ ID NO: 12.

The special technical feature of group 58 is a method of inducing expression of a heterologous gene in a germ cell comprising contacting with the expression construct comprising SEQ ID NO: 13.

Continuation of B. FIELDS SEARCHED Item 3:
EAST, STN (medline, biosis, embase, caplus)
SMC, SMC1, SMC1.beta., antisense
STIC: SEQ ID NO: 1.